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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,774	01/09/2001	Howard M. Dintzis	07265-124005	8467

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EXAMINER	
SAUNDERS, DAVID A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
757774	DINTZIS et al
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 10/14/03.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 44-52, 54-57, 59-62, 65-87 is/are pending in the application.

Of the above claim(s) 70-87 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 44-47, 49-52, 56-57, 59-61, 65-69 is/are rejected.

☒ Claim(s) 48, 54-55, 62 is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Amendment of 10/14/03 has been entered. Claims 44-52, 54-57, 59-62 and 65-87 are pending. Claims 44-52, 54-576, 59-62 and 65-69 are under examination. The amendment has entered no new matter.

The amendment has overcome previously stated issues as follows:

The rejection of claims 44-69 under 35 USC 112, 2nd paragraph.

The rejection of claims 44-68 under 35 USC 112, 1st paragraph.

The prior art rejection based upon applicant's admitted state of the art at pages 6-10; the review of the prior art mentions nothing about others having size fractionated the coupled construct (conjugate).

The following rejections of record are maintained or modified as follows:

Claim 69 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 69 is not enabled for the production of "a non-immunogenic epitope coupled construct" in step (b).

As previously noted, subsequent step (c) is required to obtain such a non-immunogenic conjugate. See page 8, lines 15+ and page 77, lines 77+ teaching that the coupling process yields high molecular weight conjugates, as a portion of the obtained constructs, which would be immunogenic. Deletion of "non-immunogenic" in step (b) would be appropriate; also insertion of --to yield a non-immunogenic epitope coupled construct-- at the conclusion of step (c) would be appropriate.

Claims 44-46, 49, 50-52, 59-61 and 65-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Barstad et al (5,268,454) for reasons of record.

Applicant deems that the rejection of record is not appropriate because Barstad et al couple a T-cell epitope deficient antigen analog to the non-immunogenic carrier, while instant step (b) couples an epitope of a T-dependent antigen to the non-immunogenic carrier. This is unconvincing because there is nothing in instant step (b) which requires that a T-cell epitope of the T-dependent antigen be coupled to the carrier. Step (b) encompasses the case in which a B-cell epitope (lacking T-cell epitopes, as taught by Barstad et al) from a T-dependent antigen is coupled to the carrier. Instant step (b) thus does not distinguish.

As to the insertion of step (c) , this does not overcome. Barstad et al teach "size fractionation" of their conjugate preparation, by dialysis using tubing with a 14 Kd cutoff. (e.g. col. 6, line 59) or by chromatography on S-200 (e.g. col. 8, lines 34-37). To overcome, insertion of --to yield a non-immunogenic epitope coupled construct-- at the conclusion of step (c) would be appropriate for both claims 44 and 69.

Claims 44, 47, 50-52, 56-57, 59-60 and 66-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Katz (4,191,668) for reasons of record.

Applicant deems the rejection is inappropriate because Katz does not teach all elements of instant claims 44 and 69. Regarding step (b), the examiner maintains that Katz teaches the coupling of epitopes of the same nature as applicant. For example, Katz teaches coupling of the haptenic/epitopic compound benzylpenicillin to a carrier (col.3, lines 55-56; col. 4, lien 62-col. 9, line 49) as does applicant (pages 123-127). Katz teaches coupling of nucleic acids to the carrier

(col. 3, line 64; col. 10, lines 15-68) as does applicant (page 67-69). Instant step (b) thus does not distinguish.

Regarding instant step (c), Katz teaches "size fractionation" of his conjugate preparation, by dialysis (e.g. col. 5, line 14 and col. 6, line 58). To overcome, insertion of --to yield a non-immunogenic epitope coupled construct-- at the conclusion of step (c) would be appropriate for both claims 44 and 69.

Applicant's arguments filed 10/14/03 have been fully considered but they are not persuasive.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 44-47, 49, 52, 60, 65 and 69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,340,460. Although the conflicting claims are not identical, they are not patentably distinct from each other because, in amended claims 44 and 69, steps (b) and (c) correspond essentially to steps (a) and (b) of issued claim1. In instant step (c) "size fractionation" is encompassed by "removing" in issued claim 1, step (b). The "comprising" language of issued claim 1 clearly opens its scope to include the provision of a sized non-immunogenic soluble carrier, as in instant

step (a). Since there are clearly common embodiments covered by instant claims 44 and 69 and issued claim 1, a terminal disclaimer is required. Rejected dependent claims 45-47, 49, 52, 60 and 65 clearly have common embodiments with issued claims 2-9.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders, PhD whose telephone number is 703-308-3976. The examiner can normally be reached on Mon-Thu from 8:00 to 5:30. The examiner can also be reached on alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 703-308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Typed 12/26/03

David a Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644